

FORM PTO-1390  
(REV. 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

2618 USOP

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5

10/018962

INTERNATIONAL APPLICATION NO.  
PCT/JP00/04034INTERNATIONAL FILING DATE  
June 21, 2000PRIORITY DATE CLAIMED  
June 22, 1999

## TITLE OF INVENTION

ACYLHYDRAZINE DERIVATIVES, THEIR PRODUCTION AND USE

## APPLICANT(S) FOR DO/EO/US

Fumio ITOH, Hiroshi HOSONO, Masaki KAWAMURA, Keiji KUBO

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☒ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☒ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98. *Copies of Ref. A1-A8*
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:
 

Copy of first page of published application

Copies of Forms 210, 301, 304, 308, 332, 101

Itemized Return Postcard

Express Mail Label No. EL 916492293 US

Date of Deposit 12/18/01

531 Rec'd

18 DEC 2001

U.S. APPLICATION NO. (if known, see 37 CFR 1.53)

10,048,964

INTERNATIONAL APPLICATION NO.  
PCT/JP0004034ATTORNEY'S DOCKET NUMBER  
2618 USOP21. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**Neither international preliminary examination fee (37 CFR 1.482)  
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO  
and International Search Report not prepared by the EPO or JPO. . . . . \$1040.00International preliminary examination fee (37 CFR 1.482) not paid to  
USPTO but International Search Report prepared by the EPO or JPO . . . . . \$890.00International preliminary examination fee (37 CFR 1.482) not paid to USPTO  
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO . . . . . \$740.00International preliminary examination fee (37 CFR 1.482) paid to USPTO  
but all claims did not satisfy provisions of PCT Article 33(1)-(4) . . . . . \$710.00International preliminary examination fee (37 CFR 1.482) paid to USPTO  
and all claims satisfied provisions of PCT Article 33(1)-(4) . . . . . \$100.00**ENTER APPROPRIATE BASIC FEE AMOUNT =****CALCULATIONS PTO USE ONLY**

\$ 890.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30  
months from the earliest claimed priority date (37 CFR 1.492(e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	50 - 20 =	30	x \$18.00	\$ 540.00
Independent claims	4 - 3 =	1	x \$84.00	\$ 84.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$280.00	\$

**TOTAL OF ABOVE CALCULATIONS =**

\$ 1,514.00

☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above  
are reduced by 1/2.**SUBTOTAL =**

\$ 1,514.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30  
months from the earliest claimed priority date (37 CFR 1.492(f)).**TOTAL NATIONAL FEE =**

\$

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be  
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +**TOTAL FEES ENCLOSED =**

\$ 1,514.00

Amount to be  
refunded:

\$

charged:

\$

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 500799 in the amount of \$ 1,514.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any  
overpayment to Deposit Account No. 500799. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card  
information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR  
1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Mark Chao, PhD, JD

Takeda Pharmaceuticals North America, Inc.

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Lincolnshire, IL 60069 USA

(847)383-3372 fax (847)383-348

SIGNATURE

Mark Chao, PhD, JD

NAME

37,293

REGISTRATION NUMBER

For Customer No. 23,115



B n b l e 1 0 9 2

10/018962

531 Rec'd PCT/

18 DEC 2001

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: tba

Filed: tba

1<sup>st</sup> Inventor: Fumio ITOH

For: Acylhydrazine Derivatives, Their Production and Use

Atty. Dkt. No. 2618 USOP

Art Unit: tba

Examiner: tba

Allowed:

Batch:

Paper No.:

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL. No. EL 916492293 US

DATE IN: December 18, 2001

**Itemized Papers/Items:**

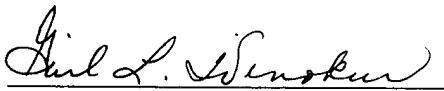
1. This certificate and a Return Receipt Postcard (2 pages)
2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
3. Copy of Request form of the International Application PCT/JP00/04034(Form PCT/RO/101)(5 pages)
4. English translation of the International Application as filed in Japanese [This includes Specification total 326 pages, including Claims 1-50 (15 pages), Abstract (1 page)]
5. Information Disclosure Statement (1 page) with Form PTO-1449 (4 pages), and copies of references (8)
6. Copy of Forms PCT/IB/301, 304, 308 and 332 (5 pages)
7. Copy of the front page of the International Application as published (WO 00/78747) (1 page)
8. Copy of International Preliminary Examination Report (English translation to follow)
9. Declaration and Power of Attorney (4 pages)
10. Assignment (2 pages) and Assignment Recordation Cover Sheet (1 page X 2)
11. Preliminary Amendment (1 page)
12. Copy of International Search Report (Form 210)(6 pages)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

BOX PCT  
Commissioner for Patents  
Washington, D.C. 20231.

on this date, 12/18/01

Dated: 12/18/01

  
Gail L. Winokur